

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

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ABBOTT GMBH & CO., KG, AND  
ABBOTT BIORESEARCH CENTER, INC.

Plaintiffs,

v.

CENTOCOR ORTHO BIOTECH, INC.,

Defendant.

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Civil Action No. 4:09-cv-11340-FDS

**Jury Trial Demanded**

**L.R. 16.1 JOINT STATEMENT**

Counsel for the parties have conferred, as required by Rule 16.1(b) of the Local Rules of this Court, and now submit this Joint Statement in accordance with Local Rule 16.1(d).

**I. NATURE OF THE CASE**

Abbott GmbH & Co., KG (“Abbott GmbH”) is the assignee of U.S. Patent No. 6,914,128 (the “’128 patent”), entitled “Human Antibodies That Bind Human IL-12 And Methods For Producing,” which issued on July 5, 2005, and the assignee of U.S. Patent No. 7,504,485 (“the ’485 patent”), entitled “Human Antibodies That Bind Human IL-12,” which issued on March 17, 2009. The subject matter that is disclosed in the ’128 and ’485 patents (collectively, the “Asserted Patents”) was developed at Abbott Bioresearch Center, Inc. (“ABC”).

In this action (“Infringement Action”), Abbott GmbH and ABC (collectively “Abbott”) allege that Centocor Ortho Biotech, Inc. (“Centocor”) infringes the ’128 and ’485 patents by making, using, selling and offering for sale its competing anti-IL-12 antibodies, known as ustekinumab, which are marketed under the tradename Stelara. Abbott seeks damages and injunctive relief. In a related action under 35 U.S.C. § 146, No. 4:10-cv-40003 (the “Centocor Section 146 Action”), Centocor challenges the priority determination by the Board of Patent

Appeals and Interferences with respect to the '128 patent. As part of that challenge, Centocor asks the court to reconsider whether the claims of the '128 patent are nonobvious over the prior art. As set forth below, Centocor's position is that resolving the Section 146 Action may lead to an early resolution of the issues in Abbott's infringement case for both the '128 patent and the closely related '485 patent.

## **II. PROPOSED PRE-TRIAL PLANS**

The parties have conferred regarding a pre-trial plan and have reached agreement on several scheduling matters. In particular, the parties consent to consolidated discovery for both the Infringement Action and the Section 146 action. The parties have been unable to reach agreement, however, as to the order in which the cases should be tried or an overall case management schedule. Accordingly, set forth below are Abbott and Centocor's respective proposed case management schedules for the Court's consideration.

### **A. Abbott's Proposed Case Management Schedule**

Abbott's proposed case management schedule contemplates that the trial of Abbott's claims that Centocor infringes the Asserted Patents in the above-captioned action will occur before any trial of the claims asserted in the *later-filed* Centocor Section 146 action. The Court should adopt Abbott's proposed schedule for the following reasons.

First, Abbott's Seventh Amendment right to a jury trial of its infringement allegations outweighs any interest Centocor may claim in proceeding first with its Section 146 Action. *See Tegal Corp. v. Tokyo Electron America, Inc.*, 257 F.3d 1331 (Fed. Cir. 2001) (entitlement to jury trial in infringement action for damages). This is particularly true in circumstances such as the present case in which Abbott filed the above-captioned action before Centocor filed its Section 146 Action and where Abbott asserts an additional patent (the '485 patent) that was not at issue

in the Centocor Section 146 Action. Accordingly, even an adverse finding on the priority issue would not eliminate the need for a trial on this second patent.

Centocor has had its opportunity to challenge Abbott's priority of invention with regard to the '128 patent. Following a twenty-month proceeding that included thousands of pages of evidence and 21 declarations regarding inventorship, the U.S. Patent & Trademark Office Board of Patent Appeals and Interferences ("Board") issued a carefully considered 100-page opinion in Abbott's favor. The Board found that Abbott's asserted actual reduction to practice (no later than June 5, 1995) pre-dated Centocor's purported reduction to practice date (no later than June 23, 1997). Centocor now seeks a do-over on the same issues decided by the Board at the expense of Abbott's right to have its earlier-filed infringement claims—including claims of infringement of a patent not implicated by Centocor's Section 146 action—heard by a jury in this Court. Centocor's attempt should be rejected.

Second, the schedule that Abbott proposes is more convenient and efficient for the Court, the parties, and their witnesses. Under Abbott's proposed schedule, discovery and evidence relevant to both actions would need to be taken, presented, and considered only once. Specifically, for example, depositions of inventors and other witnesses whose testimony is relevant to both actions could be taken only once, those witnesses' testimony would conceivably need to be presented to the court only once, and alleged prior art and evidence relating to Abbott's priority of invention would need to be presented and considered only once. *See, e.g., Biochem Pharma, Inc. v. Emory Univ.*, 148 F. Supp. 2d 11, 12 (D.D.C. 2001) ("the convenience of the parties and witnesses and the interests of justice will best be served by disposing of [] consolidated [Section 146] cases together with the underlying patent infringement action[.]").

Finally, Abbott's proposed schedule follows the common practice of district courts facing contemporaneous actions for infringement and actions under section 146. Recognizing the overlap of issues in infringement and section 146 actions (e.g., affirmative defenses of invalidity asserted in response to claims of infringement and challenges to patentability asserted in section 146 actions) and the need for consistent treatment of such issues, courts often consider infringement and section 146 actions concurrently. *See, e.g., Novo Nordisk A/S v. Bio-Technology Gen. Corp., Ltd.*, No. 02-332, 2003 WL 21383717, at \*6 (D. Del. 2003) (denying summary judgment, *inter alia*, because "both cases (the present litigation and defendants' § 146 appeal) will be tried concurrently to the court"); *Biochem Pharma, Inc. v. Emory Univ.*, 148 F. Supp. 2d 11, 12 (D.D.C. 2001) (granting motion to transfer section 146 actions because "the interests of justice will best be served by disposing of these consolidated cases together with the underlying patent infringement action.").

For all of the foregoing reasons, the court should adopt Abbott's proposed case management schedule.

**(A) Preliminary Disclosures**

**(1) Rule 26(a) Disclosures:** The parties will make their Initial Disclosures no later than **March 11, 2010**.

**(2) Preliminary Infringement Disclosure:** Not later than **March 25, 2010**, Abbott shall serve and file preliminary disclosure of the claims infringed. Abbott shall specify which claims are allegedly infringed and identify the accused product(s) or method(s) that allegedly infringe those claims. Abbott shall also specify whether the alleged infringement is literal or falls under the doctrine of equivalents. If Abbott has not already done so, it shall produce all documents supporting its contentions and/or identify any such supporting documents produced by Centocor. Such disclosures may be amended and supplemented up to thirty (30) days before the date of the Markman Hearing. After that time, such disclosures may be amended or supplemented only pursuant to ¶ D(1) or by leave of court, for good cause shown.

(3) **Preliminary Invalidity and Non-Infringement Disclosures:** Not later than **May 24, 2010**, Centocor shall serve and file Preliminary Invalidity and Non-Infringement Contentions. Centocor shall identify prior art that anticipates or renders obvious the identified patent claims in question and, for each such prior art reference, shall specify whether it anticipates or is relevant to the obviousness inquiry. If applicable, Centocor shall also specify any other grounds for invalidity, such as indefiniteness, best mode, enablement, or written description. If Centocor has not already done so, it shall produce documents relevant to the invalidity defenses and/or identify any such supporting documents produced by Abbott. Further, if Centocor has not already done so, it shall produce documents sufficient to show operation of the accused product(s) or method(s) that Abbott identified in its preliminary infringement disclosures. Such disclosures may be amended or supplemented up to thirty (30) days before the date of the Markman Hearing. After that time, such disclosures may be amended or supplemented only pursuant to ¶ D(1) or by leave of court, for good cause shown, except that, if Abbott amends or supplements its preliminary infringement disclosures, Centocor may likewise amend or supplement its disclosures within thirty (30) days of service of the amended or supplemented infringement disclosures.

(B) **Amendment of Pleadings:** Amendments to the pleadings under Fed. R. Civ. P. 15 and motions for joinder of any additional parties under Fed. R. Civ. P. 19 and 20 must be served and filed no later than **June 4, 2010**.

(C) **Claim Construction Proceedings**

(1) No later than **July 16, 2010**, the parties shall simultaneously exchange a list of claim terms to be construed and proposed constructions.

(2) No later than **August 4, 2010**, the parties shall simultaneously exchange and file preliminary claim construction briefs. Each brief shall contain a list of terms construed, the party's proposed construction of each term, and evidence and argument supporting each construction. Absent leave of court, preliminary claim construction briefs shall be limited to twenty-five (25) pages, double-spaced, of at least 12-point Times New Roman font or equivalent, including footnotes.

(3) No later than **August 13, 2010**, the parties shall simultaneously exchange and file reply briefs. Absent leave of court, reply briefs shall be limited to fifteen (15) pages, double-spaced, of at least 12-point Times New Roman font or equivalent, including footnotes.

(4) No later than **August 27, 2010**, the parties shall finalize the list of disputed terms for the court to construe. The parties shall prepare and file a joint claim construction and prehearing statement (hereafter the "joint statement") that identifies both agreed and disputed terms.

(a) The joint statement shall note the anticipated length of time necessary for the claim construction hearing and whether any party

proposes to call witnesses, including a statement that such extrinsic evidence does not conflict with intrinsic evidence.

(b) The joint statement shall also indicate whether the parties will present tutorials on the relevant technology, the form of such tutorials, and the timing for such tutorials in relation to the claim construction hearing. If the parties plan to provide tutorials in the form of briefs, declarations, computer animations, slide presentations, or other media, the parties shall exchange such materials five (5) days before the claim construction hearing. In the alternative, the parties may present tutorials through presentations by the attorneys or experts at the claim construction hearing.

(c) The joint statement shall include a proposed order in which parties will present their arguments at the claim construction hearing, which may be term-by-term or party-by-party, depending on the issues in the case.

(d) The joint statement shall limit the number of claims to be construed and shall prioritize the disputed terms in order of importance.

(e) The joint statement shall include a joint claim construction chart, noting each party's proposed construction of each term, and supporting evidence.

(D) **The Claim Construction Hearing (a.k.a. “*Markman* Hearing”):** The Court shall schedule a hearing date promptly after the filing of the joint claim construction statement.

(E) **After the Hearing**

(1) If necessary, the parties may amend their preliminary infringement/non-infringement and invalidity disclosures, noting whether any infringement or invalidity contentions are withdrawn, within thirty (30) days after the Court's ruling on the claim construction.

(2) If the fact discovery period has expired before a ruling on claim construction, and upon motion or stipulation of the parties, the Court may grant additional time for discovery. Such additional discovery shall be limited to issues of infringement, invalidity, or unenforceability dependent on the claim construction.

(3) If expert discovery has been substantially conducted before a claim construction ruling, then the Court may grant additional time for supplemental expert discovery. Such additional discovery shall be limited to issues of infringement, invalidity, or unenforceability dependent on the claim construction.

(F) **Fact Discovery:** Fact discovery will be completed no later than **October 22, 2010**.

**(G) Expert Discovery**

**(1) Opening Expert Reports:** By the later of **November 19, 2010** or 60 days after the Court's ruling on claim construction, each party shall disclose expert witnesses on issues for which the party has the burden of proof and serve reports for those experts in accordance with the Rules of Civil Procedure and the Local Rules for the United States District Court for the District of Massachusetts.

**(2) Rebuttal Expert Reports:** By the later of **December 17, 2010** or 30 days after service of the Opening Expert Reports, each party shall serve a rebuttal expert report in accordance with the Rules of Civil Procedure and the Local Rules for the United States District Court for the District of Massachusetts.

**(3) Expert Discovery:** Expert discovery will be completed by the later of **January 21, 2011** or 30 days after service of the Rebuttal Expert Reports.

**(H) Motions for Summary Judgment**

**(1)** Dispositive motions shall be filed by the later of **March 9, 2011** or 45 days after the close of Expert Discovery (though parties may file dispositive motions sooner).

**(2)** Oppositions to dispositive motions shall be filed by the later of **April 8, 2011** or 30 days after the filing of any Dispositive Motions.

**(3)** Replies in support of dispositive motions shall be filed by the later of **April 22, 2011** or 14 days after the filing of the Opposition to the Dispositive Motion.

**(I) Trial:** Abbott submits that jury selection should commence on **May 2, 2011**, with the trial to commence immediately thereafter.

**B. Centocor's Proposed Case Management Schedule**

As set forth below, Centocor proposes that the schedule proceed in stages, allowing the Court to first resolve Centocor's Section 146 Action (bench trial) *before* proceeding with a jury trial (if necessary) on the remaining issues in the Infringement Action. Centocor also proposes that discovery for the Section 146 Action be consolidated with discovery on infringement, invalidity, and unenforceability issues in the Infringement Action. After a bench trial in the Section 146 Action, Centocor then proposes that a second phase of fact and expert discovery

proceed, if necessary, on damages and willfulness. In addition, since claim construction is not required to resolve the Section 146 Action, Centocor proposes that claim construction briefing not proceed until after the bench trial. Centocor's proposal not only provides for efficient discovery, but also allows for early resolution of important issues by the Court, which may eliminate the need for further proceedings.

Centocor's proposal accounts for the fact that the long-standing dispute between the parties over priority and obviousness for the '128 patent remains unsettled. Under 35 U.S.C. § 146, Centocor is entitled to the "equitable remedy" of having this Court review of the interference proceeding between the parties. *Human Genome Scis., Inc. v. Genentech, Inc.*, 589 F. Supp. 2d 512, 515 (D. Del. 2008). The final resolution of the Section 146 issues will, at the very least, allow the parties to sensibly evaluate their positions in the Infringement Action, and may actually eliminate the need for further proceedings. Contrary to Abbott's position, the Section 146 issues are also directly relevant to all of Abbott's infringement claims for both patents.

Abbott ignores the fact that the subject matter of the '128 and '485 patents is closely related and based on the same patent specification. Contrary to Abbott's position, resolving the Section 146 Action will greatly narrow the issues in, and potentially may resolve, the infringement case for both patents. For example, a determination that Centocor is entitled to priority will moot Abbott's claims with respect to the '128 patent and will also have an effect on the invalidity of the '485 patent claims. The obviousness of the '128 patent claims is also directly relevant to the obviousness of the related '485 patent claims. At a minimum, resolution of those still-pending issues will allow the parties to determine whether it is worth moving forward with the time and expense of a jury trial. Abbott's proposal defers the issue of who has



established priority to the asserted claims until *after* those claims have already been asserted against Centocor in a full-blown jury trial.

Importantly, under Centocor's proposal, if the parties cannot resolve the case, then Abbott will be entitled to proceed to trial, with its right to a jury preserved. Abbott's proposal, on the other hand, essentially eliminates Centocor's statutory right to the equitable remedy of the Section 146 Action.

Regarding fact discovery, Centocor's proposal provides for more time to allow for adequate discovery relating to the '128 and '485 patents. First, there are 22 inventors listed on the face of these patents, who were associated with at least three different corporate entities. Second, several inventors apparently reside outside the United States, and Abbott has recently indicated that it is not aware of the current location of some of them. Centocor's proposal accounts for the need to track down those inventors and potentially proceed with discovery under the Hague Convention. Also, given the complexity of the facts associated with conception and reduction to practice for the asserted patents, Centocor also proposes an increase in the limits on depositions and written discovery as set forth below.

For these reasons, Centocor's proposed schedule, set forth below, should be adopted.

**Amendment of Pleadings:** Amendments to the pleadings under Fed. R. Civ. P. 15 and motions for joinder of any additional parties under Fed. R. Civ. P. 19 and 20 must be served and filed no later than **August 20, 2010**.

**Fact Discovery:** Fact discovery will be completed no later than **February 25, 2011**.

**Expert Discovery**

(1) **Opening Expert Reports:** By **March 25, 2011** each party shall disclose expert witnesses on issues for which the party has the burden of proof (other than damages and willfulness) and serve reports for those experts in accordance with the Rules of Civil Procedure and the Local Rules for the United States District Court for the District of Massachusetts.

(2) **Rebuttal Expert Reports:** By the later of **April 22, 2011** or 30 days after service of the Opening Expert Reports, each party shall serve a rebuttal expert report in accordance with the Rules of Civil Procedure and the Local Rules for the United States District Court for the District of Massachusetts.

(3) **Expert Discovery:** Expert discovery will be completed by the later of **May 20, 2011** or 30 days after service of the Rebuttal Expert Reports.

**Trial:** Centocor proposes that a bench trial for the Section 146 Action should commence on **June 20, 2011**.

Following the bench trial, Centocor proposes that claim construction proceed, as set forth in the Court's Local Patent Rules, from July 2011 to September 2011.

Fact and expert discovery for damages and willfulness issues would also proceed starting in July 2011, ending in October 2011. Any remaining issues would then be ready for dispositive motions and jury trial.

In the event that the Court does not agree with Centocor's proposal to conduct claim construction briefing after a Section 146 bench trial, Centocor proposes the following alternative schedule for claim construction, which unlike Abbott's proposal allows the parties the time provided under the Court's Local Patent Rules.

### **Claim Construction Proceedings**

(1) No later than **September 21, 2010**, the parties shall simultaneously exchange a list of claim terms to be construed and proposed constructions.

(2) No later than **October 11, 2010**, the parties shall simultaneously exchange and file preliminary claim construction briefs. Each brief shall contain a list of terms construed, the party's proposed construction of each term, and evidence and argument supporting each construction. Absent leave of court, preliminary claim construction briefs shall be limited to twenty-five (25) pages, double-spaced, of at least 12-point Times New Roman font or equivalent, including footnotes.

(3) No later than **October 21, 2010**, the parties shall simultaneously exchange and file reply briefs. Absent leave of court, reply briefs shall be limited to fifteen (15) pages, double-spaced, of at least 12-point Times New Roman font or equivalent, including footnotes.

(4) No later than **November 5, 2010**, the parties shall finalize the list of disputed terms for the court to construe. The parties shall prepare and file a joint claim construction and prehearing statement (hereafter the “joint statement”) that identifies both agreed and disputed terms.

(a) The joint statement shall note the anticipated length of time necessary for the claim construction hearing and whether any party proposes to call witnesses, including a statement that such extrinsic evidence does not conflict with intrinsic evidence.

(b) The joint statement shall also indicate whether the parties will present tutorials on the relevant technology, the form of such tutorials, and the timing for such tutorials in relation to the claim construction hearing. If the parties plan to provide tutorials in the form of briefs, declarations, computer animations, slide presentations, or other media, the parties shall exchange such materials five (5) days before the claim construction hearing. In the alternative, the parties may present tutorials through presentations by the attorneys or experts at the claim construction hearing.

(c) The joint statement shall include a proposed order in which parties will present their arguments at the claim construction hearing, which may be term-by-term or party-by-party, depending on the issues in the case.

(d) The joint statement shall limit the number of claims to be construed and shall prioritize the disputed terms in order of importance.

(e) The joint statement shall include a joint claim construction chart, noting each party’s proposed construction of each term, and supporting evidence.

### **III. CERTIFICATIONS**

The parties have submitted or will submit the certifications required by Local Rule 16.1(D)(3).

### **IV. TRIAL BY MAGISTRATE JUDGE**

The parties do not consent to a trial by a Magistrate Judge.

### **V. ALTERNATIVE DISPUTE RESOLUTION**

No agreement has been made at this time for consent to alternative dispute resolution, but Abbott is willing to participate in mediation following the close of discovery.

## **VI. ADDITIONAL MATTERS**

The parties will continue to confer about the form in which electronically stored information shall be produced. The parties have conferred but have been unable to reach agreement on proposed discovery event limitations.

### **A. Abbott's Proposed Discovery Event Limitations**

Abbott proposes that the parties abide by the discovery event limitations of L.R. 26.1(C) with two exceptions, as set forth below.

**Discovery event limitations:** The discovery event limitations set forth in L.R. 26.1(C) shall apply with the following exceptions: (1) each party shall be limited to 150 hours of fact witness depositions (including any Fed. R. Civ. P. 30(b)(6) deposition); and (2) each party shall be limited to one deposition under Fed. R. Civ. P. 30 (b)(6).

### **B. Centocor's Proposed Discovery Event Limitations**

As set forth above, considering the complexity of the facts surrounding the asserted patents and the 22 inventors allegedly involved, Centocor proposes that the discovery limits be as follows.

#### **Discovery event limitations:**

- a. Maximum of 40 interrogatories for each side.
- b. Maximum of 40 requests for admission for each side.
- c. Maximum of 150 individual requests for production for each side.
- d. Maximum of 250 hours of depositions of fact witnesses for each side.

Respectfully submitted,

February 18, 2010

/s/ William F. Lee

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## CERTIFICATE OF SERVICE

I hereby certify that on February 18, 2010, I electronically filed the above document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the following:

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